Zoledronic Acid (Reclast)

Criteria for Use: Osteoporosis & Paget's Disease

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VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria *If ANY item below is met, then the patient should NOT receive zoledronic acid.*

- ☐ Patient does not have a diagnosis of osteoporosis or Paget's disease or is not at risk for surgical/drug-induced osteoporosis
- ☐ Patient has a history of hypersensitivity reactions, including urticaria or angioedema, with a bisphosphonate.*
- ☐ Patient is hypocalcaemic or has a pre-existing disturbance of mineral metabolism (e.g., hypoparathyroidism, thyroid or parathyroid surgery, vitamin D deficiency, malabsorption syndromes, excision of small intestine) that has not been effectively corrected or treated.* Exception: Patients with hyperparathyroidism and low bone mineral density who are nonsurgical candidates.
- ☐ Patient has had a recent dental procedure such as a tooth extraction that increases the risk for osteonecrosis of the jaw. When in question, patients should be referred to Dental Services.*
- ☐ Patient's creatinine clearance is <35 mL/min.*

For treatment of osteoporosis only (do not apply to Paget's disease, prevention, or patient's previously treated with zoledronic acid):

- ☐ Patient has been on an oral bisphosphonate for <2 years without an osteoporotic fracture
- ☐ Patient's bone mineral density has remained stable without a clinically significant loss (a decrease of >3%) at the same anatomical site DXA compared to baseline after being on an oral bisphosphonate for ≥2 years in the absence of an osteoporotic fracture. **(See** Injectable Alternatives to Oral Bisphosphonates **Algorithm #2)**

Inclusion Criteria

General Inclusion Criteria (all must be met for all indications)

- ☐ Provider ordering zoledronic acid has examined the patient's oral cavity to screen for decay, trauma or other conditions which may increase the risk of osteonecrosis of the jaw prior to receiving each dose.* When findings are questionable, patients should be referred to Dental Services
- ☐ Patient's total daily dietary and supplemental calcium intake is 1000 to 1500 mg/day.
- ☐ Patient has a 25-hydroxyvitamin D concentration ≥20 ng/mL AND an active prescription for cholecalciferol (Vitamin D_3) or ergocalciferol (Vitamin D_2) to prevent deficiency. For example, cholecalciferol ≥800 IU per day.

PLUS ONE OF THE FOLLOWING INDICATIONS:

- ☐ Patient has experienced an osteoporotic fracture while taking an oral bisphosphonate

OR

- ☐ Patient has had an osteoporotic-related hip fracture in the past 90 days.

OR

- ☐ Patient has been on an oral bisphosphonate ≥2 years with a >3% decrease in bone mineral density on same anatomical site DXA compared to baseline. **(See** Injectable Alternatives to Oral Bisphosphonates **Algorithm #3)**

OR

- ☐ Patient has a relative or absolute contraindication to an oral bisphosphonate such as a history of upper GI injury or intolerance to an oral bisphosphonate, an increased risk for upper GI injury due to a co-morbid condition (e.g., esophageal motility disorder or Barrett's esophagus), physical condition (e.g., cannot sit-up for the required time period following oral dosing), or a nonfunctional GI tract (e.g., enteral feedings via gastric or jejunostomy tube).

OR

- ☐ Patient has a diagnosis of Paget's disease

OR

Treatment and prevention of surgical/drug-induced osteoporosis (see issues for consideration)

☐ Patient has a relative or absolute contraindication to an oral bisphosphonate such as a history of upper GI injury or intolerance to an oral bisphosphonate, an increased risk for upper GI injury due to a co-morbid condition (e.g., esophageal motility disorder or Barrett's esophagus), physical condition (e.g., cannot sit-up for the required time period following oral dosing), or a nonfunctional GI tract (e.g., enteral feedings via gastric or jejunostomy tube).

PLUS ONE OF THE FOLLOWING

☐ Patient has been or is expected to be treated with prednisone 5 mg/day (or its equivalent) for ≥ 3 months

OR

☐ Patient is receiving pharmacologic androgen deprivation therapy or has undergone orchiectomy, or an aromatase inhibitor for breast cancer

OR

☐ Patient has been or is expected to be treated with antiepileptic drugs for >2 years

*For safety these criteria should be reviewed prior to each infusion.
DXA = Dual-energy x-ray absorptiometry

Dosage and Administration

Refer to Product Information.

Issues for Consideration

- Patient's with a 25-hydroxyvitamin D concentration <20 ng/mL should receive vitamin D repletion.
- Patient adherence with an oral bisphosphonate should be assessed. Patients whose adherence is ≤80% should be receive interventions to improve adherence prior to receiving zoledronic acid.
- AEDs associated with osteoporosis: Phenytoin, carbamazepine/oxcarbazepine, phenobarbital/primidone, valproic acid/valproate
- Use in premenopausal women of childbearing potential: All bisphosphonates, denosumab and teriparatide are FDA Pregnancy Category C and should be used during pregnancy only if benefits outweigh risks. Based on animal data, bisphosphonates, denosumab, or teriparatide may cause fetal harm if administered during pregnancy. Bisphosphonates long terminal half-lives, storage in bone, and recirculation during bone remodeling after their discontinuation has raised concern about their use even before pregnancy. Consider the potential for future pregnancy when prescribing osteoporosis treatment to women of childbearing potential.

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